REMARKS

The Examiner indicated that the disclosure was objected to because the grant information on page one was left blank and because the previous priority information was not deleted. Applicants have amended the specification to update the priority information as well as provide the grant information.

Claims 29-60 were pending in the application. Claims 30, 33, 55, and 56 have been withdrawn from further prosecution as drawn to non-elected groups; these claims have been canceled without prejudice. Claim 31 has been canceled. Claims 29, 32, 34, 35, 37-48, 51-54, and 57 have been amended to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Accordingly, upon entry of the present amendment, claims 29, 32, 34-54, and 57-60 will be pending in the instant application.

Support for the amendments to the claims may be found throughout the specification and claims, as originally filed. *No new matter has been added.* Specifically, support for amendment to claim 29 can be found at least at page 29, lines 27-37 through page 30, lines 1-4; support for amendment to claim 32 can be found at least at page 30, lines 35-38 through page 31, lines 1-6; support for amendment to claim 37 can be found at least in Example 1, page 49, lines 28-38, through page 50, lines 1-23; support for amendment to claim 40 can be found at least at page 31, lines 28-31; support for amendment to claim 57 can be found at least at page 29, lines 18-21, at page 31, lines 10-23, and in Example 1, page 49, lines 28-38, through page 50, lines 1-23.

Any amendments to and/or cancellation of the claims are not to be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Rejection of Claims 29, 31, 32, 34-35, and 57-60 Under

35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 29, 31, 32, 34-35, and 57-60 under 35 U.S.C. §112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that "[c]laims 29 and 57 are vague and unclear because the effect being assayed and analyzed is not clearly set forth." In addition, the Examiner states that

> [w]ith respect to claim 57, it is noted that a cytokine is assayed, however there is no clear correlation with the effect of the compound on the cytokine and the effect on c-Maf. Because a cytokine amount or activity goes up or down in response to the administration of a compound is insufficient to determine that the compound had an affect on c-Maf. The claim is incomplete because critical steps that provide a nexus between any cytokine and c-Maf activity is not adequately set forth. Finally, the claims require the use of 'human c-maf, however c-maf is part of a large family of proteins obtainable from a variety of mammalian species each sharing a significant homo logy. No specific sequence is set forth in the instant claims, and it is unclear exactly what c-maf protein is being used, how modified in can/could be, or what uniquely defines a sequence as human.

Applicants respectfully traverse this rejection. However in the interest of an expedited prosecution, Applicants have amended claim 29 to recite ***a human c-Maf protein of SEQ ID NO.:2*** and claim 57 has been amended to recite ***a human c-Maf***

protein comprising the NheI/XbaI fragment of pHu-c-Maf (ATCC Accession No. 98671). In addition, claim 29 has been amended to more clearly claim the effect being assayed and analyzed, *e.g.*, ***the effect of the test compound on the activity of the human c-Maf protein in the indicator cell is determined by evaluating the expression of the reporter gene in the presence and absence of the test compound, to thereby identify a compound that modulates the activity of a human c-Maf protein***.

Claim 57 has similarly been amended to recite the effect of the test compound on human c-Maf activity is determined by ***evaluating the level of cytokine production in the indicator cell in the presence and absence of the test compound, wherein a modulation of the level of cytokine production identifies the test compound as a modulator of the activity of a human c-Maf protein***.

The Examiner has rejected claim 32 as being "incomplete because it does not have active steps for practicing the method as claimed. The Examiner continues, '[t]he claim is vague and unclear because what compound is being tested and what affects are being assayed are not clearly set forth in the claim, nor the specification. Further, the claim is drawn to a new method and does not further limit claim 29 because there is no specific modulation of c-Maf in claim 29 that indicates what compound should be used in the method set forth in claim 32."

Applicants have amended claim 32 and made this claim an independent claim in order to obviate the rejection of this claim as not further limiting claim 29. In addition, the present amendment to claim 32 more distinctly claims what effects are being assayed, *e.g.*, to recite that the test compound that modulates an immune response is identified by ***evaluating the effect of the compound on expression of the Th2-associated cytokine***

gene in the presence and the absence of the test compound, to thereby identify a compound that modulates an immune response.

The Examiner has rejected claim 37 as being "vague and unclear because the location of the endogenous promoter and the structural or functional metes and bounds of the promoter sequence being used is not clearly set forth." Applicants have amend claim 37 to recite that ***the regulatory sequences of the endogenous human c-Maf gene comprise the untranslated sequences of the NheI/XbaI fragment of pHu-c-Maf (ATCC Accession No. 98671).***

The Examiner has rejected claims 40 and 41 as being "vague and unclear because the sequence from which '—157 to +58' is derived not defined, nor is its context within the construct being used." The Examiner continues, "[s]imilarly, claim 41 is unclear in where the sequence ends or begins to adequately define where one would obtain 'about 3kb' of upstream sequence." Applicants have amended claim 40 to recite that positions -157 to +58 of the interleukin promotor are ***relative to the start site of transcription of +1 of the interleukin 4 gene.***

The Examiner has rejected claims 43-47 as being are "unclear in the recitation of 'derived from' because how similar or different a resulting cell should be from the cell from which it is 'derived' is not adequately set forth." Applicants have amended claims 43-47 by deleting the phrase 'derived from' from the claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Rejection of Claims 29, 31, 32, 34-35, 37-49, 51-54, and 57-60

Under 35 U.S.C. §102

The Examiner has rejected claims 29, 31, 32, 34-35, 37-49, 51-54, and 57-60 under 35 U.S.C. §102(b), as being anticipated by Hodge, *et al.* (*Mol Cell Biol*, 1995). Applicants assume the Examiner meant Hodge, *et al.* (1996) *Science* 274:1903-1905 and request clarification if this is not the case. The Examiner states that

> Hodge, *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on IL-4 expression (figure 5) and reporter genes such as CAT (figure 4). The cell types used in the assays include B cell M12B lymphoma and nonlymphoid HEPG2 cells. Because Hodge, *et al.* teach a cell based reporter assay method for assaying immune response as related to IL-4 and other reporter genes as it is related to the presence of c-Maf, the methods of Hodge, *et al.* anticipates the instant claims.

The Examiner has rejected claims 29, 31, 34, 40, and 42 under 35 U.S.C. §102(b), as being anticipated by Kataoka, *et al.* (*Mol Cell Biol,* 1995). The Examiner states that

> Kataoka, *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on the reporter activity of luciferase (see figure 9). Because Kataoka, *et al.* teach a cell based reporter assay method for assaying a reporter gene as it is related to the presence of c-Maf, the methods of Kataoka, *et al.* anticipates the instant claims.

The Examiner has rejected claims 29, 31, 34, 37, 40, 42, 43, 48 and 50 under 35 U.S.C. §102(a), as being anticipated by Hedge, *et al.* (*Mol Cell Biol*, 1995). Applicants assume the Examiner meant Hedge, *et al.* (1998) *Mol Cell Biol* 18:2729-2737 and request clarification if this is not the case. The Examiner states that

> Hedge, *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on the reporter activity of a reporter gene or in the context of a two hybrid system (see figures 1-3 and Table I). The affects of the different transcriptional factors are put in the context of differentiation of myeloid cells, thus are directly relevant to affects and modulation of the immune system (see discussion pages 2735-36). Because Hedge, *et al.* teach a cell based reporter assay method for assaying a reporter gene as it is related to the presence of c-Maf, the methods of Hedge, *et al.* anticipates the instant claims.

Applicants respectfully traverse these rejections. With respect to claim 31, Applicants have canceled this claim and thus the Examiner's rejection is moot. With respect to independent claims 29, 32 and 57 and dependent claims 34-35, 37-50, 52-54, and 58-60, Applicants submit that this rejection does not pertain to these claims as currently amended.

For a prior art reference to anticipate a claimed invention, the prior art must teach ***each and every element*** of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987). Claims 29, 32, and 57, as currently pending, and thus claims dependent therefrom, recite that the indicator composition comprises ***a human c-Maf protein of SEQ ID NO.:2*** (claims 29 and 32) or ***a human c-Maf protein comprising the NheI/XbaI fragment of pHu-c-Maf (ATCC Accession No. 98671)*** (claim 57). Hodge, *et al.*, Kataoka *et al.*, and Hedge, *et al.* either alone or in combination, do not teach or suggest each and every limitation of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejections.

CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call the undersigned at (617) 227-7400.

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Respectfully submitted,

By _____

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